

Unproven cell clinics continue to damage the public reputation of regenerative medicine and promise of stem cell therapies – what else can be done?

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Many concerned members of the International Society for Cellular Therapy-ISCT have committed substantial resources and time to the problem of unproven cell therapies. The creation of the ISCT Presidential Task Force and a series of publications over many years all attest to the commitment made to curb the false advertising and direct-to-consumer marketing of futile or potentially-harmful cellular interventions (<http://www.celltherapysociety.org/?page=PTF2015>). And yet we and others have clearly documented the growth and widespread distribution of stem cell tourism and clinics that continue to pedal false hope for their own financial benefit (Cell Stem Cell. 2016 Aug 4;19(2):158-62. doi: 10.1016/j.stem.2016.07.015). National regulators, health ethicists and medical professionals in many jurisdictions have been constrained by inadvertent legal loopholes and playing “whack-a-mole” - whereby a given clinic may be shut down only to reappear in a similar guise elsewhere. Concerned voices have had a substantial effect in shutting down rogue clinics such as the German XCell Center for Stem Cell Therapy and the Italian Stamina Foundation, where former ISCT President and current Chair of the mentioned ISCT Presidential Task Force, Massimo Dominici, had a role in curtailing illegitimate activities.

“We shall continue to call attention to the fraudulent approaches where patients are badly informed and mistreated with so-called stem cell treatments. These alleged treatments do not offer even the most minimal evidence of scientific background to support those approaches,” states Massimo Dominici, *“This recent work published by Prof. Rasko, Prof. Sipp and others certainly sheds additional light over this dark side of cellular therapy and, as scientific community, we are very grateful for the effort. More must be done to protect patients. The only chance to achieve that is to work with different stakeholders to build public credibility regarding all these initiatives. I really think credibility is key to ultimately provide trustworthy information to patients and their associations before they make useless, extremely costly, and even dangerous decisions.”*

However, in general, the “bottom-up” approach seems to have had little effect on the proliferation of unproven stem cell clinics based predominately around autologous adipose-derived extracts.

Consequently a group of 15 international ethicists, physicians, patient advocates and scientists joined together in December 2015 in Switzerland to focus further attention on how to curtail these global activities. Our Perspective just published in *Science Translational Medicine* calls for harmonisation of global and national regulatory guidelines, increased engagement between public outreach initiatives and professionals, and more rigorous enforcement (<http://stm.sciencemag.org/lookup/doi/10.1126/scitranslmed.aag0426>). We have emphasized the importance of a parallel “top-down” approach that depends

on active participation by organisations such as the International Council on Harmonisation (ICH) and the World Health Organisation (WHO). Such organisations with international clout can organise national authorities to disseminate and establish guidelines in the same way that is accepted for medicines and medical devices. In addition we have identified 'tokens of legitimacy' that rogue clinics have often used to imply credibility in the stem cell field. These include attempts to join established academic or professional societies to suggest legitimacy by association and the frequent use of celebrity testimonials and endorsements without clinical trial evidence.

We are confident that the combined bottom-up and top-down approaches will provide a more-effective approach in addressing this growing problem.